



February 3, 2015

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Inari Medical, Inc.
c/o Mark Job
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K143563

Trade/Device Name: Infusion Aspiration Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: December 2, 2014
Received: December 16, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

Infusion Aspiration Catheter System

Indications for Use (Describe)

The Infusion Aspiration Catheter System consists of the Infusion Wire Catheter, Aspiration Guide Catheter, and Retraction Aspirator Device. The Infusion Aspiration Catheter System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Infusion Aspiration Catheter System is intended for use in the peripheral vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(K) SUMMARY

Date prepared	November 30, 2014
Name	Inari Medical, Inc. 8 Argonaut, Suite 100 Aliso Viejo, CA 92656 949.598.0300 x114
Contact person	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Trade name	Infusion Aspiration Catheter System
Common name	Embolectomy catheter
Regulation Name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	DXE
Regulatory class	II
Predicate devices	Genesis Medical Interventional F.A.S.T. System (K040010) Fogarty Thru-Lumen Embolectomy Catheter (K892410) Fogarty Venous Embolectomy Catheter (510[k] unknown)
Description	<p>The Infusion Wireform Catheter consists of a single lumen Delivery Catheter containing a second internal catheter. The internal Wireform Catheter has a hollow flexible shaft with self-expanding wireform disks attached to its distal end. The wireform disks are available in 3 sizes for treatment of vessels with diameters of 6-10 mm, 11-14 mm, or 15-18 mm.</p> <p>The Aspiration Guide Catheter is introduced over a previously placed 0.035" exchange length guidewire. A dilator compatible with the 0.035" guidewire is provided for the Guide Catheter to assist in its advancement.</p> <p>The Dilator/Guide Catheter assembly is advanced in the patient's vasculature to a location proximal of the obstruction. The dilator is withdrawn and replaced with the Infusion Wireform Catheter which is advanced distal to the obstruction. The wireform disks are deployed by retracting Delivery Catheter.</p> <p>By aspiration and withdrawal of the Infusion Wireform Catheter into the Guide Catheter, the obstructing material may be disrupted or removed.</p> <p>The Retraction Aspirator Device is available to facilitate the simultaneous aspiration and withdrawal of the Infusion Wireform Catheter into the Guide Catheter. The hand-lever operated Retraction Aspirator Device is fitted with a</p>

vacuum syringe and collection container. Operating the Retraction Aspirator Device lever simultaneously retracts the Infusion Wireform Catheter into the Guide Catheter and aspirates fluids.

Indications for use

The Infusion Aspiration Catheter System consists of the Infusion Wireform Catheter, Aspiration Guide Catheter, and Retraction Aspirator Device. The Infusion Aspiration Catheter System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Infusion Aspiration Catheter System is intended for use in the peripheral vasculature.

Summary of
substantial equivalence

The Infusion Aspiration Catheter System and the predicate devices have the same intended use: removal of obstructing material (including emboli and thrombi) from blood vessels. The Indications for Use of the Infusion Aspiration Catheter System is a subset of that of the F.A.S.T. System. The F.A.S.T. System has additional uses in synthetic grafts and temporary blood vessel/graft occlusions. The Fogarty Thru-Lumen Embolectomy Catheter (“FTLEC”) is indicated for vessels in the arterial system while the Fogarty Venous Embolectomy Catheter is indicated for the venous system. The F.A.S.T., FTLEC, and Fogarty Venous Thrombectomy Catheter are also indicated for temporary occlusion of blood vessels.

Lacking temporary use in vessel occlusions and synthetic grafts does not affect the safety or effectiveness of the Infusion Aspiration Catheter System when used as labeled.

The principle of operation is the same for Inflation Aspiration Catheter and F.A.S.T. Systems – expanding Nitinol braids are withdrawn through the vessel obstruction to restore blood flow. While the FTLEC and Fogarty Venous Thrombectomy Catheters are withdrawn through the vessel obstruction, they differ in that it is an elastomeric balloon that is being withdrawn. In all cases, the principle of operation is the same.

The Infusion Aspiration Catheter and the F.A.S.T. Systems have similar materials of construction. Both use Nitinol metal features to remove the obstruction and have thermoplastic polymer catheter shafts. Again, they differ from the FTLEC which has a latex balloon. The effect on the vessel caused by the Inflation Aspiration Catheter System was demonstrated to be similar to that of the FTLEC in the study entitled: *A GLP Evaluation of the Inari Embolectomy Device in a Bovine Model*. The Infusion Aspiration Catheter and the F.A.S.T. Systems carry the same hazard of a broken or protruding Nitinol wire causing vessel puncture. To mitigate this possibility, the Wireform Catheter is 100% inspected for broken and protruding Nitinol braids during manufacture.

The range of vessel diameter treated for the Infusion Aspiration Catheter System

(6 mm – 18 mm) is within the combined ranges of the predicate devices (5 mm – 19 mm).

The Infusion Aspiration Catheter System is provided with a 20 Fr Guide Catheter. The F.A.S.T. System, FTLEC, and Fogarty Venous Thrombectomy Catheters are used with commercially available guide catheters which can be smaller than 20 Fr. The larger Infusion Aspiration System's guide catheter limits the range of vessels it can be used in. The restriction of vessels sizes does not affect the effectiveness of the Infusion Aspiration Catheter System as demonstrated in the consistent removal of simulated thrombus from the simulated vessels in testing.

Non-Clinical Testing

In alignment with the Design Failure Modes and Effects Analysis, verification and validation testing was identified to support the safety and effective of the Infusion Aspiration Catheter System.

This testing demonstrated compliance with relevant standards (e.g. ISO 10555-1, ISO 594-1/2, etc.) and product specifications. These tests included:

- Package integrity and accelerated aging inspection
- Pouch bubble emission
- Pouch peel, seal strength
- Visual and dimensional inspections
- Guidewire compatibility
- Snap fit, Dilator Luer to Guide Catheter hemostasis valve
- System flexibility and torque
- Retraction force of Wireform Catheter into Delivery Catheter
- Deployment force of Wireform Catheter from Delivery Catheter
- Guide Catheter/Dilator kink radius
- Retraction force of Wireform Catheter into Guide Catheter
- Leakage testing, hemostasis valves with guidewire
- Guide Catheter/Infusion Wireform Catheter kink radius
- Liquid leakage under pressure (300 kPa)
- Leakage testing, devices with Guide Catheter hemostasis valve
- Test of conical fittings with 6% Luer taper
- Air leakage into hub assembly during aspiration
- Suction volume, RA device
- Retraction, RA device (15 cycles)
- Tube set, leakage
- Suction and exhaust check valve testing
- Power injection testing
- Determination of flow rate through catheter
- Tensile strength
- Corrosion resistance
- Particulate matter
- Burst Pressure
- Simulated Use Tracking

Biocompatibility testing in accordance with ISO 10993-1:

- MEM elution
- Guinea pig maximization sensitization
- Intracutaneous toxicity
- Acute systemic toxicity
- Material mediated pyrogen
- Hemolysis, direct contact and extract method
- Complement activation
- Thrombogenicity
- Mutagenicity

The shelf life of the Infusion Aspiration Catheter System is six (6) months from the date of manufacture based on accelerated aging studies. Verification testing was conducted on sterilized (ethylene oxide), accelerated-aged devices to support the 6 months shelf life.

Package integrity testing was conducted according to ISO 11607-1/2 guidelines. These tests included:

- Pouch bubble emission
- Pouch peel, seal strength

Acute evaluation of the safety and performance of the Inari Infusion Wireform Catheter, Aspiration Guide Catheter, and the Retraction Aspirator Device were successfully performed in a bovine model.

Clinical testing was not required for the determination of substantial equivalence.

Conclusion

Test results demonstrated that all acceptance criteria were met, and, therefore, the device conforms to expected device performance and intended use.

Based upon the technology, materials, intended use, non-clinical testing, and animal study results, it is concluded that the Infusion Aspiration Catheter System is substantially equivalent to the F.A.S.T. System, Fogarty Thru-Lumen Embolectomy Catheter, and Fogarty Venous Thrombectomy Catheter. These results demonstrate that the Infusion Aspiration Catheter System is as safe, as effective, and performs as well as or better than the legally marketed predicate devices identified above.